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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,645	06/04/2001	Paul D. Taylor	P-633	4460
25732	7590	05/19/2004	EXAMINER	
KEITH JOHNSON, ESQ. TRANSGENOMIC, INC. 12325 EMMETT STREET OMAHA, NE 68164			SHEINBERG, MONIKA B	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/873,645

Applicant(s)

TAYLOR ET AL.

Examiner

Monika B Sheinberg

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Detailed Action.

DETAILED ACTION

Response to Amendment filed January 8, 2004

1. Applicants' arguments, filed January 8, 2004, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are reiterated or newly applied. They constitute the complete set presently being applied to the instant application.
2. The cancellation of claims 1-12 and 17-27 is acknowledged.
3. Claims 13-16 are pending.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. The rejection of claims 13-16 is maintained and reiterated under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 U.S.P.Q. 546 (B.P.A.I. 1986) and reiterated by the Court of Appeals in In re Wands, 8 U.S.P.Q. 2d 1400 at 1404 (C.A.F.C. 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The Board also stated that although the level of skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Claims 13-16 are rejected under 35 U.S.C. § 112, first paragraph, lack of enablement. It is acknowledged the claimed method executes the adjusting, normalizing and shifting profiles as a means of transforming the chromatographic elution profiles in order to better group the resulting profiles based on shape. However, absent is the intended goal that would be achieved through the implementation of the instantly claimed method. For instance after “shifting profiles along said first axis”: 1) what does the information represent/mean of shifted profiles? 2) what distinguishes the shifted profiles from the profiles placed originally in the coordinate system?; 3) what does one do with the information? 4) what criteria(s) establishes the determination of “transformed profiles” as a “single group”, not a group at all or divided into multiples groups. Further, with respect to the grouping of profiles: 1) what does a group of profiles represent/mean? 2) what distinguishes one group over another besides having a different “total value”? 3) once grouped what does one do with the data generated data set? Thus, one skilled in the art would not understand what the transformed profile means and what to do with the information after rearranging data of an original profile; nor would one skilled in the art understand what grouping such transformed profiles would mean and what to do with the group. Additionally, the above rejection corresponds to the system that carries out the above method (claims 13-16) and computer readable medium that would execute the method. No guidance, direction, or examples are provided such that one skilled in the art would have known how to use the claimed invention. The example provided is applied to a single nucleotide polymorphism (SNP) analysis in a generic manner wherein the example demonstrated sample preparation and run with little description to the profile analysis other than stating that the program was done. Thus the example is not directed to enabling one skilled in the art to know how to perform the method steps of the profile analysis as required by the instant application. In addition, the specification states itself that its method lacks predictability as for example in its application to the analysis of SNPs: the method does not indicate a unique profile per SNP; different mutations can be grouped together just because they have the same profile shape yet are completely

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different, and that sometimes a mutation will not fall within a group at all. (see page 27, line 1-27).

However, in using the present invention, Applicants have unexpectedly discovered that it is not true that each profile implies a unique SNP.

FIG. 4 schematically shows, in a hypothetical example, the relationship of a series of SNPS to their DMIPC elution pattern. In using the methods and devices of the instant invention as described herein, Applicants have surprisingly found that in some cases, different mutations can give the same elution profile. For example, the mutations shown at 180, 182, 184 all give the same pattern as shown at 186.

A DNA fragment having a new (previously unidentified) mutation, such as shown at 188, may give an elution profile that is indistinguishable from any of the existing (previously identified) profiles, such as shown at 186, 190 and 192. Another possibility is that the DNA fragment having a new mutation could yield an elution profile that is different from existing profiles.

Even upon selecting a profile that does not fall within a group, the method and instant application *fail to indicate how a distinction would be made* for the profile to be representative of a new mutation or simple one of the ‘different mutations’ that happened to have a different profile unlike the ‘different mutations’ that had the same or even similar profiles. Given the lack of descriptive working examples in the specification, and the unpredictability of utilizing the transformed chromatographic transformed profiles, the specification, as filed is not enabling for the method of using transformed profiles for the method or system of grouping such profiles as claimed. As such, claims drawn to the use of “transformed profiles” are not enabled.

Response to arguments

6. On page 10, 3rd paragraph of the response: Applicant asserts, “one of skill in the art could routinely compare profiles of interest using the claimed system”. This argument is rendered moot for reasons that the system instantly claimed does not perform any steps of comparison.

7. On pages 10-11, bridging paragraph: Applicant asserts that the system “allows the profiled to be created which can be viewed and analyzed in a standardized format”. This argument has been thoroughly reviewed however not found persuasive because the specification fails to teach what distinctions found in the viewed profiled would lead to a meaningful result. The specification fails to enable one skilled in the art to know how or why an analysis would be useful if the distinctions that identify the profile, whether to be similar or unique, have not been

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taught by the specification. In addition, as noted in section #5, the specification states itself that its method lacks predictability as for example in its application to the analysis of SNPs: the method does not indicate a unique profile per SNP; different mutations can be grouped together just because they have the same profile shape yet are completely different, and that sometimes a mutation will not fall within a group at all. Thus, even if a comparison were to be done by the skilled artisan, what information that can be derived from the comparison and it's meaning would remain as data without meaning.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. The rejection of claims 13-16 is reiterated and maintained under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 and all claims dependent therefrom are vague and indefinite due to the lack of clarity in the action intended by the terms “transform”, “transformed” and “transforming”. It is unclear as what the profiles are being transformed from and what the profiles are being transformed into. Clarification is requested via clearer claim wording.

Response to arguments

10. On page 11, 2nd paragraph: Applicants assert that the amendment to the claims “so that the profiles can be viewed and analyzed in a standardized format” (claim 13, lines 2-3) has clarified the vagueness of stemmed from the term “transform”. This is not found to be persuasive because the lack of clarity remains in what the profiles are being transform *from* and what the profiles are being transformed *into*, aside from a rearrangement of data.

NEW GROUNDS FOR REJECTION AS NECESSITATED BY AMENDMENT

Claim Rejections - 35 USC § 112

11. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 13-16 are rejected as necessitated by amendment under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 13 has been amended to included the following recitation “so that the profiles can be viewed and analyzed in a standardized format” (lines 2-3 and 30-31). The specification as originally filed does not teach or suggest what is intended or meant by the term “standardized format” as presently claimed. As such claim 13 and all claims dependent therefrom contain new matter.

12. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

13. Claims 13-16 are rejected as necessitated by amendment under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is vague and indefinite due to the lack of clarity of the term “standardized format” (lines 3 and 31). It is unclear as to what are the metes and bounds of the parameters that define a “standardized format”, what is regarded as the form of standardization, and what the format is directed to. As such claims 14-16 are also indefinite due to dependency from claim 13.

Conclusion

MAINTAINED

- The rejection of claims 13-16 is maintained and reiterated under 35 U.S.C. 112, first paragraph.

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- The rejection of claims 13-16 is maintained and reiterated under 35 U.S.C. 112, second paragraph.

NEW, AS NECESSITATED BY AMENDMENT

- Claims 13-16 are rejected under 35 U.S.C. 112, first paragraph.
- Claims 13-16 are rejected under 35 U.S.C. 112, second paragraph

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The central **Fax number is (703) 872-9306**.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monika B. Sheinberg, whose telephone number is (571) 272-0749. The examiner can normally be reached on Monday-Friday from 9 A.M to 5 P.M. If attempts to reach the examiner by telephone are unsuccessful, the primary examiner in charge of the prosecution of this case, Jehanne Sitton, can be reached at (571) 272-0752. If attempts to reach the examiners are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Patent Analyst, Chantae Dessau, whose telephone number is (571) 272-0518, or to the Technical Center receptionist whose telephone number is (703) 308-0196.

May 13, 2004
Monika B. Sheinberg
Art Unit 1634

MBS

Jehanne Sitton
JEHANNE SITTON
PRIMARY EXAMINER
5/17/04